In the Claims

40. (Currently amended) A therapeutic composition for treating the effects of HIV infection comprising at least one fraction separated from a sample comprising urine which comprises naturally occurring ~~of native~~ hCG and/or ~~native~~ β-hCG, ~~wherein the native hCG or native β-hCG has not being purified to homogeneity; and~~ wherein the at least one fraction comprises naturally occurring hCG and/or β-hCG and has an approximate molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD as determined by elution from a gel filtration sizing column relative to the elution of a naturally occurring ~~native~~ hCG heterodimer with a molecular weight of 77 kD, and a β-hCG core protein or peptide with a molecular weight of 10 kD~~, and is active in inhibiting HIV infection and replication~~.

42. (Currently amended) A therapeutic composition produced by a process comprising the following steps:

a) subjecting a sample comprising urine which comprises naturally occurring ~~native~~ hCG or ~~native~~ β-hCG to a size fractionation procedure, ~~wherein native hCG or native β-hCG has not being purified to homogeneity~~; and

b) recovering fractions that are effective in the treatment of HIV infection, wherein the recovered fractions comprise naturally occurring hCG and/or β-hCG and contain material having an approximate molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD, and wherein the molecular weight is determined by elution from a gel filtration sizing column relative to the elution of a naturally occurring hCG heterodimer, having a molecular weight of 77 kD, and a β-hCG core protein or peptide, having a molecular weight of 10 kD. ~~inhibit HIV infection and replication.~~

43. (Cancelled)

44. (Previously amended) The therapeutic composition of claim 42, wherein the sample is early pregnancy urine.

45. (Withdrawn to be rejoined and currently amended) A method for producing a therapeutic composition for treating the effects of HIV infection ~~having anti-HIV effects~~, said method comprising:

a) subjecting a urine sample comprising naturally occurring ~~native~~ hCG or ~~native~~ β-hCG to a size fractionation procedure; ~~native hCG or native β-hCG has not being purified to homogeneity;~~ and

b) recovering fractions comprising naturally occurring hCG and/or β-hCG and that are effective in the treatment of HIV infection ~~active to inhibit HIV infection or replication.~~

46. (Withdrawn to be rejoined and previously amended) The method of claim 45 wherein the size fractionation procedure comprises the steps:

a) loading the sample onto a gel filtration sizing column in a first buffer of 30 mM sodium phosphate, pH 8.3;

b) eluting components of the sample from the column with second buffer of 30 mM sodium phosphate, pH 7.0 and 2 M sodium chloride; and

c) recovering fractions of the sample having been eluted from the column.

47. (Withdrawn to be rejoined and original) The method of claim 45 wherein the gel filtration sizing column is a SUPERDEX 200™ column and wherein the recovered fractions contain material having an approximate molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD, wherein the molecular weight is determined by elution from the SUPERDEX™ 200 column relative to the elution of a native hCG heterodimer, having a molecular weight of 77 kD, and a β-hCG core protein or peptide, having a molecular weight of 10 kD.

48. (Withdrawn to be rejoined and previously amended) The method of claim 47 wherein the sample is early pregnancy urine.

49. (Withdrawn to be rejoined and previously amended) The method of claim 48 wherein prior to subjecting the urine to a size fractionation procedure, the sample is subjected to the following steps:

a) adjusting the pH of the urine to a pH of approximately 7.2 causing the formation of a precipitate;

b) removing the precipitate from the urine;

c) concentrating the urine;

d) removing salt and lipid from the urine; and

e) lyophilizing the urine.

68. (Withdrawn to be rejoined and currently amended) A method of treating the effects of an HIV infection in a human subject in need of such treatment comprising:

administering to the subject an effective amount of a therapeutic composition comprising at least one fraction separated from a urine sample comprising ~~of~~ naturally occurring ~~native~~ hCG and/or ~~native~~ β-hCG ~~that has not being purified to homogeneity~~, and wherein the one fraction has an approximate molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD determined by elution from a gel filtration sizing column relative to the elution of a naturally occurring ~~native~~ hCG heterodimer with a molecular weight of 77 kD, and a β-hCG core protein or peptide with a molecular weight of 10 kD and is active in treating the effects of HIV infection. ~~inhibiting HIV infection and replication.~~

D6

71. (Currently amended and withdrawn to be rejoined) A method of treating the effects of HIV infection ~~reducing replication of HIV~~ in a human subject in need of such treatment comprising:

administering to the subject an effective amount of a composition to treat HIV infection, the composition being produced by a process comprising the following steps:

a) subjecting an early pregnancy urine sample comprising naturally occurring ~~native~~ hCG or ~~native~~ β-hCG to a size fractionation procedure~~, wherein the native hCG or native β-hCG has not being purified to homogeneity~~; and

b) recovering fractions that comprise naturally occurring hCG and/or β-hCG and contain material having an approximate molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD, wherein the recovered fractions treat the effects of HIV infection. ~~exhibit anti-HIV effects.~~

D7

72. (Cancelled)

73. (Withdrawn to be rejoined and original) The method of claim ~~72~~ 71 wherein the molecular weight is determined by elution from a gel filtration sizing column relative to the elution of a naturally occurring ~~native~~ hCG heterodimer, having a molecular weight of 77 kD, and a β-hCG core protein or peptide, having a molecular weight of 10 kD.

D8

82. (Previously amended) A pharmaceutical composition comprising

a) a therapeutic composition of claim 40; and

b) a pharmaceutically acceptable carrier.

D9

83. A pharmaceutical composition comprising

a) a ~~protein or peptide~~ therapeutic composition of claim 42; and

b) a pharmaceutically acceptable carrier.

84. (Currently amended) A therapeutic composition comprising at least one fraction separated from a urine sample comprising naturally occurring ~~of native~~ hCG or ~~native~~ β-hCG, wherein the ~~naturally occurring native~~ hCG or ~~native~~ β-hCG has not being purified to homogeneity~~,~~ wherein the at least one fraction has an approximate molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD when separated using sizing column chromatography, and wherein the at least one fraction is active in treating the effects of an HIV infection. ~~inhibiting HIV infection and replication.~~

85. (Previously added) A pharmaceutical composition comprising

a) a therapeutic composition of claim 84; and

b) a pharmaceutically acceptable carrier.

D9

86. (Currently amended) A therapeutic composition comprising at least one fraction separated from a sample of early pregnancy urine comprising naturally occurring ~~native~~ hCG and/or ~~native~~ β-hCG, wherein the natural occurring ~~native~~ hCG and/or ~~native~~ β-hCG has not being purified to homogeneity, and wherein the at least one fraction contains naturally occurring hCG and/or β-hCG and material having an approximate molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD and is active in treating the effects of HIV infection. ~~inhibiting HIV infection and replication.~~